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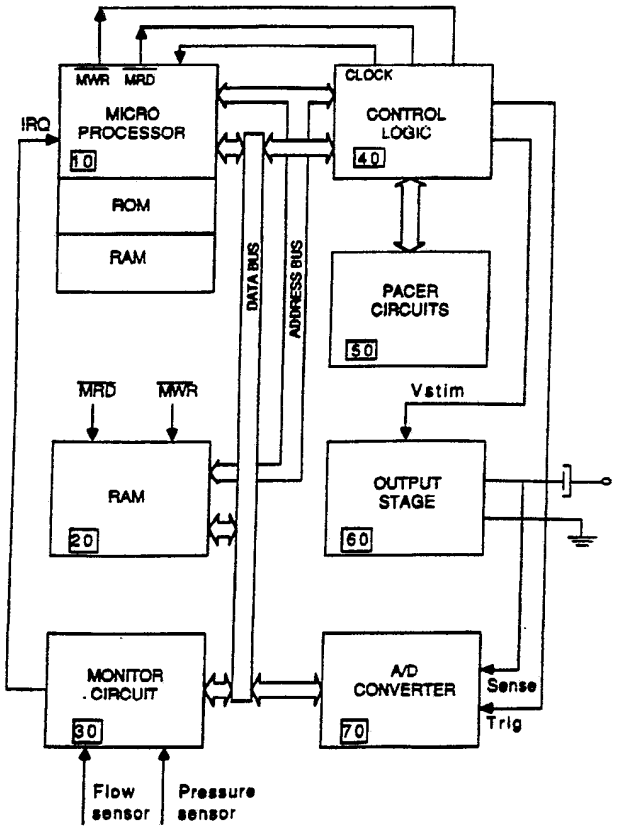
(54) Title: PACEMAKER SYSTEM

(57) Abstract

An implantable pacemaker system comprises a pulse generator having a memory function and an electrode to be introduced into the heart of a patient. The electrode is connected to the pulse generator via an implantable electrode lead. The system monitors intracardiac ECG. The pulse generator stores the ECG thus monitored in its memory continuously, so that the memory holds ECG data relating to a predetermined elapsed period of time. Means detect death or syncope of the patient and in response thereto stop the storage procedure, at least after a second predetermined period of time has elapsed following said detection.



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PACEMAKER SYSTEM

Transvenous intracardiac stimulation with an implanted pacemaker is an established and common treatment for certain cardiac arythmias. The intention with this treatment is to keep the patient free from symptoms and if possible to prevent an too early death. The simplicity of the surgical intervention allows rather wide indications for this kind of treatment.

Many patients (12-40%) faint or die suddenly and unexpectedly in spite that they are provided with a pacemaker that functions well. This sudden and unexpected syncope or death can occur at any time and place.

Often the relatives refuse an autopsy. However, even if an autopsy is performed it is often impossible to find the cause of sudden death except in cases of lungemboli, recent cardiac infarction or a cardiac or vascular rupture. The cause of an unexpected syncope may also be difficult to ascertain afterwards.

Cardiac pacemakers from many manufactures are today able to sense and to store certain parameters such as the numbers of electrical impulses for stimulation of the heart, which may or may not produce cardiac contractions, and also to store the electrical activity (Ecg) of the spontaneous cardiac rythm. These registrations can be recorded and printed out from an implanted pacemaker with a help of telemetry. Likewise the parameters that are to be registered can also be programmed from the outside through telemetry.

Before a patient with an implanted pacemaker is burried or cremated it is generally demanded that the impulse generator is removed from the body. According to the invention is is suggested that the pacemaker system is constructed in such a way that the pacemaker senses and records the cardiac rythm i.e. the intracardiac Ecg at least at the time of death or syncope and also during a predetermined time (for instance 48 hours) before the event and that this recording later can be

read out from the impulse generator, preferably after it has been removed from the body or alternatively with the use of telemetry while the impulse generator still remains in the patient.

According to a preferred construction the cardiac rythm after death or syncope is recorded during a predetermined time. This time period may for instance be of the magnitude 10 minutes up to 1 hour. With this kind of construction it is advantageous to have the pacemaker to record the time of sensed death or syncope relative to other recordings in such a way that one with certainty can separate recordings before and after sensed death or syncope.

The fact that the thus recorded cardiac rythm, i.e. pacemaker induced or spontaneous rythm, may be studied afterwards thus makes it possible to obtain better clarification of the cause of death or syncope.

Death occurs when the heart has ceased to pump blood out into the circulation, i.e. when circulation stops. Circulation, i.e. the flow of blood is kept up by the pumping capacity of the heart. By means of its pumping capacity the heart of a living person produces a flow of blood, pulsations and a blood pressure.

According to the invention one of these signs of circulation is preferably taken advantage of in order to verify the particular recordings of the pacemaker. More specifically, the disappearing of such a sensed sign of circulation at death or syncope is used to secure the recording according to the invention.

Methods or techniques for the sensing of pressure, flow or pulsations for instance in an artery are available and are easily applicable. Such parameters can also be obtained from a vein. The sensing of one of these parameters, may either be taken from the outside of the vessel or from its inside. A dissection and visualization of a vessel such as an artery is a simple surgical procedure especially during an operation upon the heart on a patient when at the same time a pacemaker

is to be implanted. Sensors which for instance are placed on to or into an artery can easily be connected with the pacemaker for instance through an implanted conductor lead.

The pumping of the heart can also be sensed directly inside the heart with a suitable sensor, such as a pressure sensor, which preferably can be integrated with and introduced together with an electrode belonging to the pacemaker system.

It is of course also possible to have the pacemaker sense the electric activity of the heart (Ecg) in a suitable way, a detected disappearing or change of such electric activity during a certain period then securing the desired recording according to the invention.

It should be realized that the memory capacity of the impulse generator for recordings according to the invention preferably should be such that it corresponds to the total time during which recording should be done. When the memory is full the oldest recordings should automatically be removed in order to give space for new recordings according to a rolling schedule.

The pacemaker system according to the invention will now be described in more detail by way of an exemplifying embodiment while referring to the enclosed drawing, the single figure of which shows a schematic block diagram of a pacemaker system embodying the invention.

Block 10 is a microcomputer hereafter referred to as MCU. A preferred MCU for use in the application of this invention as a part of a programmable cardiac pacer is the HD6301 micro processor made by Hitachi. It offers design advantages of high speed, extremely low power consumption, internal 16 bit timer and registers.

An external 8 bit address bus and an 8 bit bidirectional parallel data bus are used for all patrallel data communications between CPU and external logic, memory, etc. There are timing signals Clock, MRD, MWR and IRQ.

Clock is the principle timing signal, input from a

clock found in the control logic block 40 and controlled by logic within that controller.

The frequency of the clock may be up to 2 Mhz, but for this application is 76.8 Khz. IRQ is an input for the MCU and when activated it will start a sequence or action initiated by the monitor circuit block 30. The remaining pins are control pins, only two of which are illustrated here. MRD and MWR control the memory operation.

Although only internal ROM and RAM of MCU 10 and one RAM block 20 are shown, it is understood that there is no limitation on the amount of memory, subject only to design considerations. As further shown in the Fig. the output of control logic block 40, which is a timing signal presented as Vstim, is connected to a conventional or advanced output stage block 60 for developing an output signal to be delivered to a patient's heart.

It is to be understood that for a pacer application other conventional circuitry is incorporated, including timing logic for determining the rate and circumstances for delivering output pulses; an input path for receiving means for receiving external program signal and modifying operating parameters in accordance with such external signals; etc. All these functions are conventional and well described in the patent literature, and are represented by pacer circuits block 50 which is shown communicating with control logic block 40. The A/D converter represented by block 70 is used to convert the measured input signal into a digital 8 bit word, the timing and measuring intervals being controlled by control logic block 40. For the measuring intervals in application, it is understood that there is no limitation on the speed, subject only to design considerations. Measuring interval in this application is 3.33 msec. An 8 bit word representing the value of the input signal related to time is via the data bus transported for storage into RAM 20 where it replaces in a location pointed by the MCU previous measured data. Usage of a RAM capacity of 64 Kbytes, which requires

two commercially available as 32 Kbyte circuits, allows then approx. 218 sec history storage of intracardiac signals.

Storage of data is arranged in such a way by the micro-computer program that the oldest available data is replaced by the last measured data.

Replacement of data will be halted in case one of the situations as described in the claims will occur.

Flow and pressure sensor detection means as used in claims 2 and 3 are conventional and well described in the patent literature.

Monitoring the change of the electrical activity of the heart in response to death of the patient can be done by means of morphology recognition on slew rate by using the calculated moving average.

Alterations and modifications are of course possible within the scope of the invention as defined by the following patent claims. For instance the pacemaker system may also include a function for cardiac defibrillation.

CLAIMS

1. An implantable pacemaker system, comprising a pulse generator having a memory function and at least one electrode to be introduced into the heart of a patient, preferably transvenously, the electrode being connected to the pulse generator via an implantable electrode lead, ***characterized*** in that it is arranged - in a manner previously known per se - to monitor intracardiac ECG; the pulse generator is arranged continously to store the ECG thus monitored in its memory so that the memory holds ECG data relating to a predetermined elapsed period of time; and means are arranged for detecting death or syncope of the patient and in response thereto to stop said storage procedure, at least after a second predetermined period of time has elapsed following the detection of the death or syncope of the patient.

2. A pacemaker system according to claim 1, ***characterized*** in that said monitoring means are arranged for monitoring a parameter dependent on the pumping activity of the heart.

3. A pacemaker system according to claim 2, ***characterized*** in that said monitoring means are arranged to monitor a circulation parameter, such as blood pressure, blood flow or pulsations.

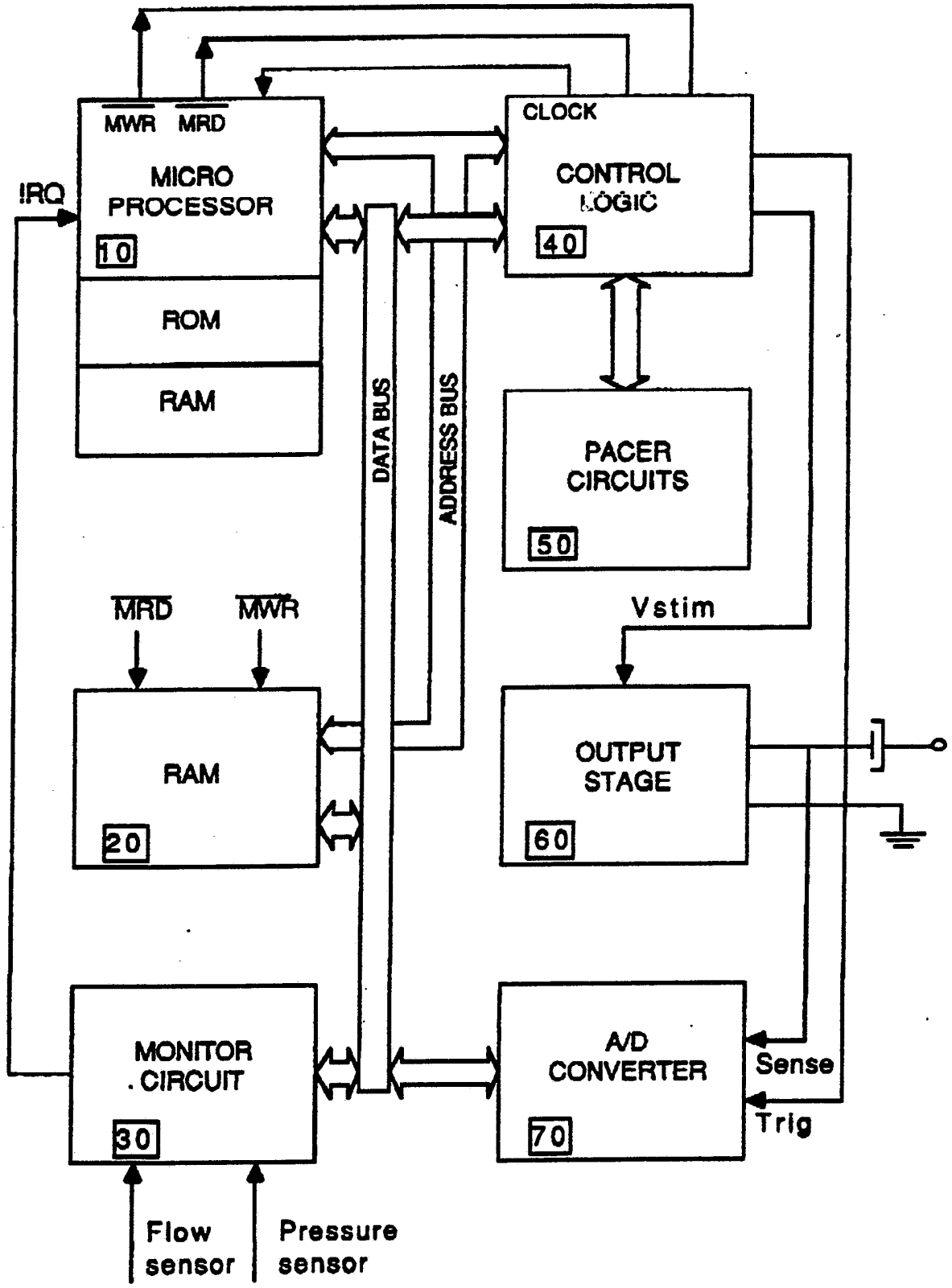
4. A pacemaker system according to claim 3, ***characterized*** in that said monitoring means comprise a sensor adapted for being applied in conjunction with an artery and connected to the pulse generator via an implantable connection lead.

5. A pacemaker system according to claim 1, ***characterized*** in that said monitoring means are arranged for monitoring a change of the electrical activity of the heart responsive to the death or syncope of the patient.

6. A pacemaker system according to claim 1, 2 or 5, ***characterized*** in that said monitoring means comprise a sensor to be introduced into the heart and connected to the pulse generator via an implantable connection lead.

7. A pacemaker system according to claim 6, ***characterized*** in that said connection lead and said electrode lead are integrated.

8. A pacemaker system according to anyone of the preceding claims, ***characterized*** in that the pulse generator is arranged to store the time of the detection of the death or syncope of the patient relative to said ECG data.


MWR
MRD
MICRO PROCESSOR
10
IRQ
ROM
RAM
CLOCK
CONTROL LOGIC
40
DATA BUS
ADDRESS BUS
PACER CIRCUITS
50
MRD
MWR
Vstim
RAM
20
OUTPUT STAGE
60
MONITOR . CIRCUIT
30
A/D CONVERTER
70
Sense
Trig
Flow sensor
Pressure sensor

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE88/00446

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC [4]

A 61 N 1/362

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 4	A 61 N 1/36, 1/362-1/378
US Cl	128:419P, 419PG, 419PT, 695-700, 702-712

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4 513 743 (VAN ARRAGON ET AL) 30 April 1985 See col. 1, lines 50-63, col. 7, lines 39-60	1-8
A	US, A, 4 601 291 (BOUTE ET AL) 22 July 1986	

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1988-11-10	1988 -11- 15
International Searching Authority	**Signature of Authorized Officer**
Swedish Patent Office	Anders Holmberg

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